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10/049,761	02/07/2002	Clark T. Hung	20076.73	7596

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EXAMINER

BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 12/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No. 10/049,761		Applicant(s) HUNG ET AL.	
Examiner William H. Beisner		Art Unit 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-29 and 31-60 is/are rejected.
- 7) ☒ Claim(s) 30 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: . |

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DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 18 Nov. 2002 has been considered and made of record.

Claim Objections

2. Claim 29 is objected to because of the following informalities: In claim 29, step (c) ends with a period. A claim should be written as a single sentence. Appropriate correction is required.

3. Claim 30 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

Note claim 30 as written depends from claim 29 and claim 1.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 11, 28, 29 and 31-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In claim 11, “the fluid pressurization” lacks antecedent basis. Note claim 1 does not employ this language. It appears that this claim should depend from claim 6 rather than claim 1.

In claim 28, “the loading platens” lacks antecedent basis. Claim 1, from which this claim depends, is silent as to the presence of “platens”.

In claim 29, line 12, “said stressed cell-seeded scaffold” lacks antecedent basis. The previous language of this claim is devoid of the word “stressed”.

In claim 59, “the loading platens” lacks antecedent basis. Claim 29, from which this claim depends, is silent as to the presence of “platens”.

In claim 60, “the shaped tissue” lacks antecedent basis. Note claim 58 recites means for producing shaped tissue not claim 59.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 1-6, 13 and 20-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Peterson et al.(US 6,121,042).

With respect to claim 1, the reference of Peterson et al. discloses a bioreactor device that includes a growth chamber (10, 50, 100, 150) and means for applying hydrostatic (18,30) and deformational loading (12, 54, 56, 154) to a cell-seeded scaffold (20) held within the growth chamber.

With respect to claims 2-5, the growth chamber is capable of holding any type of scaffold material. Note claim 1 does not positively recite the scaffold as part of the claimed device.

With respect to claim 6, pump (30) can provide pulsatile flow (See column 4, line 66, to column 5, line 12).

With respect to claim 13, the device is also capable of applying an intermittent cyclic deformational loading (See column 6, lines 48-67).

With respect to claim 20, as discussed with respect to claims 6 and 13 above, the device is capable of providing both types of loading.

With respect to claim 21, the device is capable of modifying the loads over time in response to changes in the density of the construct (See column 7, lines 1-5).

With respect to claims 22-25, in the absence of further positively recited structure, the device would be capable of providing the claimed tissue.

With respect to claims 26 and 27, the device supports the scaffolds within the growth chambers with holding means so as to produce a tissue of a desired shape of a body part to be replace and/or repaired.

8. Claims 1-5, 13, 22-29, 31, 32, 34, 35, 45 and 58-60 are rejected under 35 U.S.C. 102(e) as being anticipated by Fofonoff et al.(US 5,882,929).

With respect to claim 1, the reference of Fofonoff et al. discloses a bioreactor device that includes a growth chamber (44) and means for applying deformational loading (72, 14) to a cell-seeded scaffold (26, 30) held within the growth chamber.

With respect to claims 2-5, the growth chamber is capable of holding any type of scaffold material. Note claim 1 does not positively recite the scaffold as part of the claimed device.

With respect to claim 13, the device is also capable of applying an intermittent cyclic deformational loading (See column 8, lines 18-38).

With respect to claims 22-25, in the absence of further positively recited structure, the device would be capable of providing the claimed tissue.

With respect to claims 26-28 and 58-60, the device supports the scaffolds within the growth chambers with holding means so as to produce a tissue of a desired shape of a body part to be replace and/or repaired. (See the platens 14 and 22).

With respect to claim 29, the bioreactor contains scaffold material is impregnated with chondrocyte cells (See column 2, lines 30-44).

With respect to claims 31, 32 and 34, the reference discloses the use biocompatible and bioabsorbable materials (See column 2, lines 20-29).

With respect to claim 35, the resulting constructs mature into replacement cartilage tissue (See column 2, lines 44-52).

With respect to claim 45, the deformational loading is cyclic (See column 9, lines 23-43).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 7-12 and 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al.(US 6,121,042).

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The reference of Peterson et al. has been discussed above.

While the reference of Peterson et al. disclose the use of cyclic hydrostatic pressurization and/or loading of the construct held within the growth chamber, the reference is silent as to the specifics of the cyclic treatments in terms of pressures, deformation, frequency and/or length of time.

The reference of Peterson et al. discloses that the object of the treatment system is to expose the tissue constructs to loading that resembles the physiological conditions typically encountered by the tissue being replace and/or repaired (See column 6, lines 63-67).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine the typical conditions that the desired tissue would be exposed to and operate the device to mimic those physiological conditions in terms of loading, frequency and length of time.

13. Claims 14-19, 33, 46-51 and 54-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fofonoff et al.(US 5,882,929).

The reference of Fofonoff et al. has been discussed above.

With respect to claims 14-19 and 46-51, while the reference of Fofonoff et al. disclose the use of cyclic loading of the construct held within the growth chamber, the reference is silent as to the specifics of the cyclic treatments in terms of pressures, deformation, frequency and/or length of time.

The reference of Fofonoff et al. discloses that the object of the treatment system is to expose the tissue constructs to loading that resembles the physiological conditions typically encountered by the tissue being replace and/or repaired (See column 2, lines 30-52).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine the typical conditions that the desired tissue would be exposed to and operate the device to mimic those physiological conditions in terms of loading, frequency and length of time.

With respect to claim 33, while the reference of Fofonoff et al. prefers to use bioadsorbable material, the use of synthetic biocompatible material is known (See column 1, lines 28-35). As a result, it would have been obvious to one of ordinary skill in the art to use synthetic material for the scaffold for the known and expected result of providing an alternative means recognized in the art to achieve the same result, supporting the cultured tissue for implantation.

With respect to claims 54-57, while the reference is silent as to the specific cartilage produced, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine the specific type of cartilage produced based merely on the intend use of the cartilage in terms of the location in the body it is intended to be implanted.

14. Claims 6-12, 20, 21, 36-44, 52 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fofonoff et al.(US 5,882,929) in view of Peterson et al.(US 6,121,042).

The reference of Fofonoff et al. has been discussed above.

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Claims 6, 20, 36, 37, 38 and 52 differ because they require that the device and method of use also provide a means for hydrostatic loading of the scaffold material.

The reference of Peterson et al. discloses that it is known in the art to provide a bioreactor device with both a means for deformational loading and hydrostatic loading of tissue constructs within the bioreactor chamber. Specifically, the reference of Peterson et al. discloses a bioreactor device that includes a growth chamber (10, 50, 100, 150) and means for applying hydrostatic (18,30) and deformational loading (12, 54, 56, 154) to a cell-seeded scaffold (20) held within the growth chamber.

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Fofonoff et al. in include hydrostatic loading as suggested by Peterson et al. for the known and expected result of providing an additional means recognized in the art for ensuring that the cultured cells are exposed to conditions that mimic physiological conditions and for improving the contact of the culture medium within in pores of the porous scaffold material during the culture process.

With respect to claims 7-12 and 39-44, while the reference of Peterson et al. disclose the use of cyclic hydrostatic pressurization and/or loading of the construct held within the growth chamber, the reference is silent as to the specifics of the cyclic treatments in terms of pressures, deformation, frequency and/or length of time.

The reference of Peterson et al. discloses that the object of the treatment system is to expose the tissue constructs to loading that resembles the physiological conditions typically encountered by the tissue being replace and/or repaired (See column 6, lines 63-67).

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In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine the typical conditions that the desired tissue would be exposed to and operate the device to mimic those physiological conditions in terms of loading, frequency and length of time.


With respect to claims 21 and 53, the reference of Peterson et al. discloses that it is known in the art to a modify the loads over time in response to changes in the density of the construct (See column 7, lines 1-5). As a result, it would have been obvious to one of ordinary skill in the art to modify the loads of the modified primary reference over time for the known and expected result of responding to changes in the density of the tissue construct during the culture process.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006 (571-272-1269 after 12/16/03). The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920 (571-272-1281 after 12/16/03). The fax phone number for the organization where this application or proceeding is assigned is 703-872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.


William H. Beisner
Primary Examiner
Art Unit 1744